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Immediate implants with buccal defects filled with bone from the tuberosity or a xenograft: 1-year randomized trial

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Abstract: The aim of this study was to compare the use of autologous bone from tuberosity (TUBER) and deproteinized bovine bone mineral (DBBM) in immediate implants with buccal bone defects. A total of 31 patients with one single tooth in the upper anterior region indicated for extraction presenting tomographic buccal bone defect were analyzed. Immediate implantation was conducted for all patients. In one group, DBBM and a collagen membrane were inserted into the buccal defect; in the other group, a small block of bone from tuberosity was used. The primary outcome was facial-palatal ridge thickness (FPT) measured in casts 1 year after function. The implant success rate was 100% in both groups. FPT changes were <0.5 mm and did not differ significantly between groups. FPT reductions in the DBBM and TUBER groups were 1% and 0.6%, respectively, at the gingival margin and 5% and 2%, respectively, at 6 mm apical of the gingival margin ($p > 0.05$). No significant differences were observed between groups for patient's esthetic, satisfaction, pain and quality of life. Pink esthetic scores for the DBBM and TUBER were 11.5±1.7 and 10.8±1.9, respectively (p=0.37). It can be concluded that DBBM and TUBER did not differ in terms of ridge alterations, peri-implant clinical parameters and patient-reported outcomes.

Keywords: Bone Substitutes; Alveolar Bone Grafting; Esthetics.

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Introduction

Dimensional changes in the alveolar process after tooth extraction have been documented, and immediate implants alone have failed to prevent such changes.[1,2] Contrarily, immediate implant installation together with gap filling, minimally invasive extraction, three-dimensional prosthetically guided implantation and use of immediate provisionalization demonstrated predictable functional and esthetic outcomes to replace teeth.[3-7]

Immediate implants have been indicated only in fresh extraction sockets with an intact buccal bone wall.[8-10] However, treatment protocols that allow highly predictable and little traumatic successful outcomes, preferable in one single surgery, have been pursued in implantology. In this regard, immediate implant installation in sockets with buccal bone defects has been proposed in some case reports[11,12] and case series.[13-15]

Also, one clinical trial[16] compared immediate and delayed implants in sockets with buccal defects ³ 5 mm and found no differences after one years in regards of marginal bone levels. Overall, initial findings from these publications suggest that in the presence of a buccal bone defect at the moment of immediate implant installation, the bone defect may be reconstructed in the same surgical act of implant installation.

Since there is very scarce data regarding this therapeutic approach, there are no comparative studies regarding which graft may be used to reconstruct the buccal defect. The use of autologous bone from the tuberosity has been proposed[12,16] due to its easiness of obtaining, compared to other autologous donor areas, and to its biological properties.[17] Differently from other autologous techniques, the Immediate Dento-alveolar Restoration technique (IDR) consists of the removal of a cortical block from the tuberosity, which is placed by juxtaposition in the buccal defect of the implant serving as a cortical shield. Some advantages of applying autologous bone grafts include its biological properties serving as a high reservoir of bone formation cells being considered the gold-standard in various regenerative procedures in Dentistry, its lower cost, and the facility to obtain the appropriate size of the graft in a block format leading to easier rebuild of the alveolar contour and convexity.

Nevertheless, there is controversy on this approach because the literature recommends the use of grafts of slow resorption to counteract dimensional changes.[18-20] For example, the use of deproteinized bovine bone mineral (DBBM) with a collagen membrane has been advocated for the repair of the buccal bone defect simultaneously with the installation of immediate implants in a publication of case series.[15] DBBM has also been considered one of the main choices for bone regeneration in other situations in implant dentistry.[21]

The aim of this study was to compare autologous bone graft from the tuberosity and a xenogenic bone substitute to reconstruct buccal bone defects in immediate implants in terms of alveolar ridge alterations, peri-implant clinical parameters and patient satisfaction.

Methodology

This study was a parallel-design, single blinded, randomized controlled trial, registered in ClinicalTrials.gov under the record number NCT03202030. The first recruitment was conducted in March 2015, and the last patient evaluation was performed in April 2019.

Male and female individuals, 35–65 years of age, in good general health, attending a Postgraduate Implant Residency of the Faculty of Dentistry at the University of the Republic of Uruguay (UdelaR) and a private clinic in Montevideo, Uruguay, were considered eligible for the study. To be included in the study, individuals had to present one single tooth in the upper anterior region (between second premolars) indicated for extraction. Neighboring teeth had to be present and periodontally healthy without interproximal bone loss. Also, the gingival margin of the eligible tooth had to be at the same level of the neighboring teeth. Eligibility to perform immediate implantation was assessed using cone-bean computerized tomography (CBCT) provided during the screening visit. Intact bone should be present at the palatal wall and at least 5 mm apically to the apex of the tooth. The buccal bone wall was evaluated in the same CBCT, and teeth presenting a defect of at least one third of the root were considered eligible. The size of the buccal defect was further confirmed and measured during the surgical procedure of implantation, as described below.

Although the study protocol was approved before the definition of periodontitis using staging and grading has been proposed, we chose to apply the most recent criteria in this report. Therefore, patients included did not have periodontitis at stages II, III or IV.[22] Importantly, bleeding on probing was < 10%. Patients were not included in the study if they reported to smoke more than 10 cigarettes per day or were under medical treatment that could affect the osseointegration or repair of the grafts, such as diabetes, osteoporosis and/or some immunosuppression.

Ethics

The present study was conducted according to the principles of Helsinki for the conduction of studies with humans. The ethics committee of UdelaR, Uruguay, approved the present study (#281/15). All

patients were informed about the study objectives and provided written informed consent.

Interventions

Once the patients fulfilled the inclusion criteria, a diagnostic cast was obtained by an impression with alginate (Jeltrate Plus, Dentsply, Charlotte, USA) to plan the position of the final prosthetic crown. A diagnostic wax-up was designed, and the cast was duplicated. Then, a surgical guide was prepared using acrylic resin.

One experienced researcher (GSB) performed all surgical and prosthetic treatments. All patients were treated with an immediate implant with a flapless approach. Before tooth extraction, the periodontal phenotype was determined dichotomously.[23] If the probe was visible through the gingiva, a thin phenotype is attributed, whereas a thick phenotype is attributed if the probe is not visible.

Terminal anesthesia was conducted using 3% mepivacaine with 1:100,000 epinephrine. Minimally invasive extraction of the selected tooth was performed without causing damage to the papillae and to alveolar walls. Thereafter, analysis and measurement of the defect with a periodontal probe (PCP 15 UNC, Hu-Friedy, Chicago, USA) was performed in the mesial-distal and apex-coronal directions. The apical size of the defect was measured considering the palatal wall as the reference point at the coronal level.

Thereafter, the surgical guide was placed in position. Conical implants with internal connection (Osseotite Certain prevail, Biomet 3i, Palm Beach Gardens, USA) were installed. Perforation of the palatal wall was conducted according to the implant manufacturer, under constant refrigeration with saline solution, at a maximum speed of 1,200 rpm. Optimal three-dimensional position of the implant was primarily determined by a distance of 3mm from the desirable gingival margin. In the majority of the cases, implant shoulder ended in an intra-bony position, although this was not mandatory.

All cases were planned to receive immediate provisionalization. This was determined to be possible when primary stability of the implants reached ³35 Ncm. Then, a temporary abutment was installed, and immediate provisionalization was conducted with an acrylic facet to achieve a correct emergency profile. If the torque achieved was < 35 Ncm, an individualized healing cap was placed, which warranted the maintenance of interproximal and buccal soft tissue contour and stability. In this case, an adhesive provisional crown was installed using the two neighboring teeth as pillars. Importantly, the installation of the provisional crown or healing cap was made only after the placement of the grafts for each group, as described below.

In the autologous bone block group, the IDR was conducted, consisting of a block from the tuberosity.[12,14] A mucoperiosteal incision was performed on the edge of the ridge at the tuberosity with a blade #12, followed by the detachment of a full thickness flap. A corticocancellous bone graft was removed with appropriate straight chisels. After removal, manipulation of the graft was performed quickly (not more than 5 minutes) to maintain cell viability and bone vitality. The graft was modelled with alveolotomes according to the size of the buccal defect previously measured. The graft was stabilized in the buccal defect by juxtaposition with the cortical bone turned toward the soft tissue. Any space remaining between the implant and the graft was filled with cancellous bone removed from the tuberosity using Buser's curettes. Reposition of the flap and suture with nylon 5.0 were performed in the donor area.

In the DBBM group, a collagen membrane (Bio-Guide, Geistlich, Zurich, Switzerland) was adapted between the buccal soft tissue and bone defect, and an inorganic bovine bone graft imbedded in a collagen matrix (Bio-Oss collagen, Geistlich, Zurich, Switzerland) was inserted.

All patients from the two groups received dexamethasone 4mg one hour before the surgery and 875 mg of amoxicillin orally every 12 hours for 7 days after the surgery. For post-operative analgesia, ibuprofen 600 mg was prescribed orally every 8 hours, in the presence of pain.

The postoperative evaluations took place seven days after the surgery when the sutures were removed, and monthly up to 4-6 months for both groups. After 6 months, a definite cemented ceramic crown was

installed without over contour to avoid compression of the peri-implant soft tissue margin.

Outcomes

The primary outcome of this study was the facial-palatal ridge thickness. Impressions were taken with addition silicone (Panasil Ultradent, Salt Lake City, USA) before tooth extraction. Casts were then obtained with special gypsum stone type IV (Fujirock, GC, Alsip, USA). The same procedure was repeated after six months of implant placement, *i.e.* immediately after the placement of the definite crown, which comprised the baseline assessment. Subsequently, the impressions were carried out 12 months after crown installation. Casts were measured by a dentist not involved in the study with a digital caliper according to the technique described by Tarnow et al.[24] Three reference points were measured from the free gingival margin to the apex at the implant site and in the contralateral tooth: 0 mm, 3 mm and 6 mm.

Reliability of the caliper measurements was evaluated before the start of the study with repeated measures conducted in 10 casts from patients not included in the study. Measurements were made in the same three reference points as in the study, resulting in 30 measurements. These measurements were made with a one-week interval between them to avoid recall memory of the examiner. Intra-class correlation coefficient was calculated to assess the reproducibility of the measurements, resulting in a coefficient equal to 0.97.

The implant survival was also determined after 1 year, applying Albrektsson's criteria[25] as the absence of pain, dysesthesia and mobility. A clinical examination was also carried out at the 1-year appointment by a blinded clinician which was not involved in the study. Probing depth (PD) and bleeding on probing (BOP) were assessed at six sites of the implant. Although the study protocol was developed before the release of the criteria defined in the 2017 World Workshop of Periodontology (WWP) to determine peri-implant health/disease, we chose to apply the most recent criteria in this report. Therefore, peri-implant health and disease were determined according to established criteria from the consensus report of the 2017 WWP.[26] The esthetic clinical outcomes were assessed by the Pink Esthetic Score (PES).[27] The reliability of this clinical assessment was evaluated by duplicate measures after a 1-week interval, yielding a kappa coefficient of 0.9.

Pain was recorded using a VAS scale of 100mm, with end points indicating "completely no pain" and "worst pain possible." Pain was recorded 24 and 48 hours after surgery. The type and quantity of analgesics used by the patient was also recorded.

Patient-centered outcomes included esthetic satisfaction and quality of life. Patient satisfaction was recorded using a 100 mm VAS scale, with end points indicating "completely satisfied with the aesthetic result" and "totally unhappy with the aesthetic result". This assessment was made at the final evaluation of each patient. Oral health related quality of life was measured using the Spanish version of the Oral Health Impact Profile scale (OHIP-14). OHIP scores were recorded before implant installation and one year after function.

Randomization and allocation concealment

An assistant not involved in the study was responsible for the randomization procedures. Patients were randomized to test and control groups by simple randomization, performed using a random sequence of numbers generated online (www.randomization.com). Patients were then identified by numbers, which were concealed in opaque envelopes, opened at the moment of the surgery. Randomization codes were kept veiled until the statistical analyses had been performed. The researcher involved in outcome assessment was blinded to patient identity.

Sample size

As no previous study had directly compared IDR with other therapeutic alternatives, the sample size was estimated using data from Tarnow et al. [24], considering the facial-palatal ridge thickness as the primary outcome in a superiority design. A difference in facial-palatal ridge thickness in favor of the autologous block bone compared to DBBM of 1mm was considered, with a standard deviation of 0.8 mm. Alpha and beta errors of 5% and 10%, respectively, were applied. Taking into consideration the t distribution and these previous parameters, it was estimated that 15 patients per group would

be needed. Considering a possible drop-out rate of 10%, it was estimated that a sample of 17 patients per group would be necessary.

Statistical analysis

Comparisons between the two groups for facial-palatal ridge thickness (FPT) were made by the independent samples t-test. FPT was analyzed at the implant site, at the contralateral tooth, by the difference between the implant and the contralateral tooth, and by the percentage change in FPT at the implant site from baseline to 12 months [(12 mFPTi -baselineFPTi)/baselineFPTi]*100. All these variables were normally distributed, and all assumptions for the t-test were respected.

Secondary outcomes included VAS scores for pain after 24 and 48 hours, compared using the Mann-Whitney U test due to skewed data. Moreover, between-groups comparisons for PD, BOP and PES were made using the independent samples t-test.

To account for baseline differences between groups in predictors of the ridge width, multivariable analysis for the primary outcome (difference between FPT measured at the implant site and at the contralateral tooth) was conducted using generalized estimating equations (GEE) with identity link, Gaussian family and exchangeable correlation. Simple and the final multiple models were reported.

Data analysis was performed using a statistical software (Stata 14 for Macintosh, Stata Corporation, College Station, USA). The individual was the unit of analysis, and the alpha level was set at 5%.

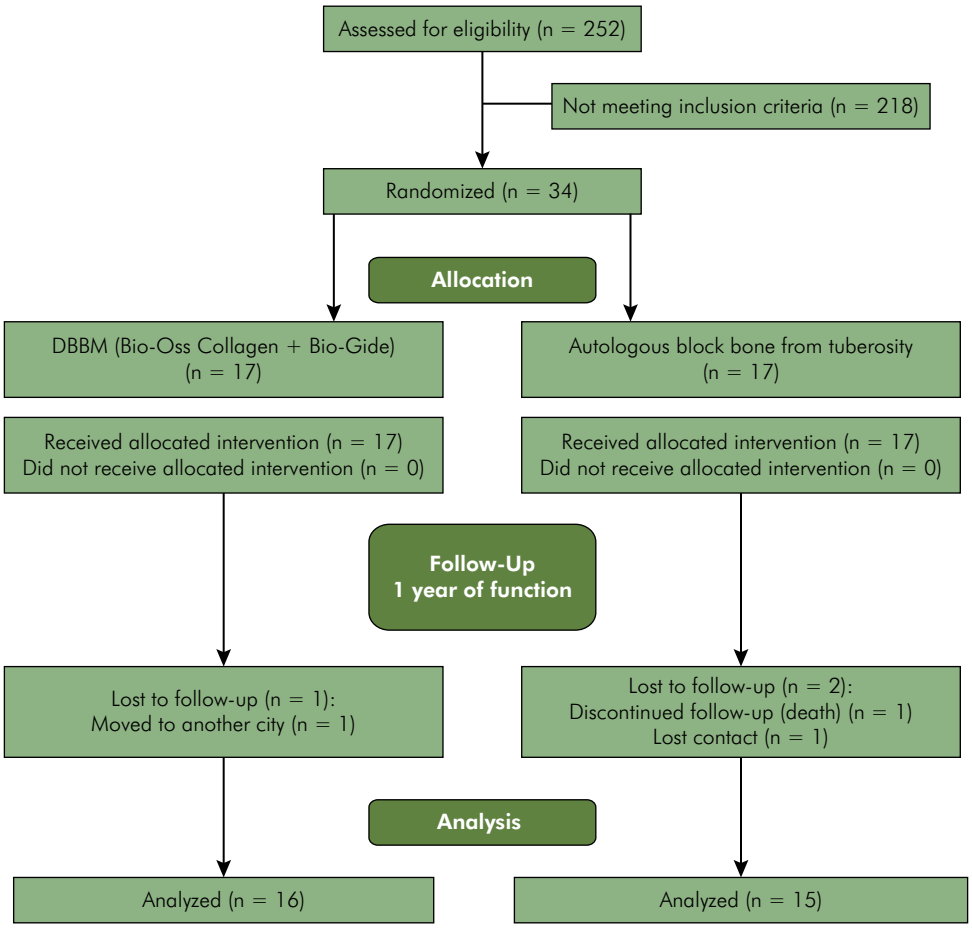

Figure 1. CONSORT flow diagram of study sample.

Results

Randomization took place for 34 patients, 17 in each group (Figure 1). In the DBBM group, one patient moved to another city and could not be reached for follow-up visits. In the autologous block group, one patient died during the follow-up period by a reason not related to the study, and another patient could not be reached or contacted. Then, a total of 31 patients were analyzed.

Characteristics of the study sample are described in Table 1. The majority of the implants were installed in the central incisor site. Two cases in DBBM group and one case in the autologous block group could not receive immediate provisional crown due to torque equal to 30 Ncm (p = 1.00). Bone defects were larger in the autologous than in the DBBM group, but with small clinical relevance not overcoming 1 mm.

There were no significant differences between groups at baseline and at 12 months in FPT at the implant site (Table 2). FPT measured at the gingival margin (0 mm) was 7.4 mm in the two groups at baseline (p = 0.99) and 7.3 mm (p = 0.95) after 12 months. There were no significant differences between groups in terms of the changes from baseline to 12 months of follow-up in FPT, which were all bellow half millimeter. There were also no significant differences in FPT between groups at the contralateral control teeth.

Overall, ridge thickness was always lower at the implant site than at the contralateral tooth. This is evidenced by the negative values in Figure 2A, showing a similar magnitude of loss in autologous block and DBBM groups, since there were no significant differences between them at baseline. The difference between the contralateral tooth and implant site was -0.5 mm in DBBM group and -0.4 mm

Table 1. Patients' characteristics in autologous and bovine bone groups.

Variable	DBBM (n = 16)	Autologous (n = 15)	p-value
Age (years)	55.6 ± 11.8	51.1 ± 8.0	0.24
Sex			
Male	6 (37.5)	4 (26.7)	
Female	10 (62.5)	11 (73.3)	0.70
Tooth position			
Central incisor	10 (62.5)	13 (86.7)	
Canine	2 (12.5)	1 (6.7)	
Pre-molar	4 (25.0)	1 (6.7)	0.41
Implant diameter			
3.25 mm	1 (6.3)	1 (6.7)	
4.0 mm	15 (93.7)	14 (93.3)	1.00
Implant length			
10 mm	0 (0.0)	1 (6.7)	
11.5 mm	1 (6.3)	0 (0.0)	
13 mm	14 (87.5)	13 (86.7)	
16 mm	1 (6.2)	1 (6.6)	1.00
Immediate provisionalization			
Yes	14 (87.5)	14 (93.3)	
No	2 (12.5)	1 (6.7)	1.00
Apical size of buccal defect (mm)	8.9 ± 2.2	9.9 ± 1.7	0.17
Mesio-distal size of buccal defect (mm)	4.9 ± 0.6	5.5 ± 0.9	0.03

Table 2. Facial-palatal ridge thickness (FPT), in millimeters, in autologous bone block and DBBM groups at the implant site and at the contralateral tooth measured at three different distances from the free gingival margin.

Distance from the gingival margin	DBBM (n = 15)	Autologous (n = 16)	p-value
0 mm			
Contralateral tooth	7.8 ± 1.0	7.7 ± 1.2	0.73
Implant site at baseline	7.4 ± 1.1	7.4 ± 0.7	0.99
Implant site 12 months	7.3 ± 1.1	7.3 ± 0.5	0.95
Difference from baseline to 12 months	-0.1 ± 0.3	-0.1 ± 0.4	0.92
3 mm			
Contralateral tooth	10.7 ± 1.3	10.4 ± 1.2	0.56
Implant site at baseline	9.9 ± 1.4	9.9 ± 0.8	0.97
Implant site 12 months	9.6 ± 1.4	9.6 ± 0.8	0.97
Difference from baseline to 12 months	-0.3 ± -0.5	-0.3 ± 0.5	0.87
6 mm			
Contralateral tooth	12.5 ± 1.5	11.7 ± 1.2	0.11
Implant site at baseline	11.8 ± 1.6	11.6 ± 0.9	0.64
Implant site 12 months	11.6 ± 1.5	11.1 ± 1.0	0.27
Difference from baseline to 12 months	-0.3 ± 0.5	-0.5 ± 0.5	0.10

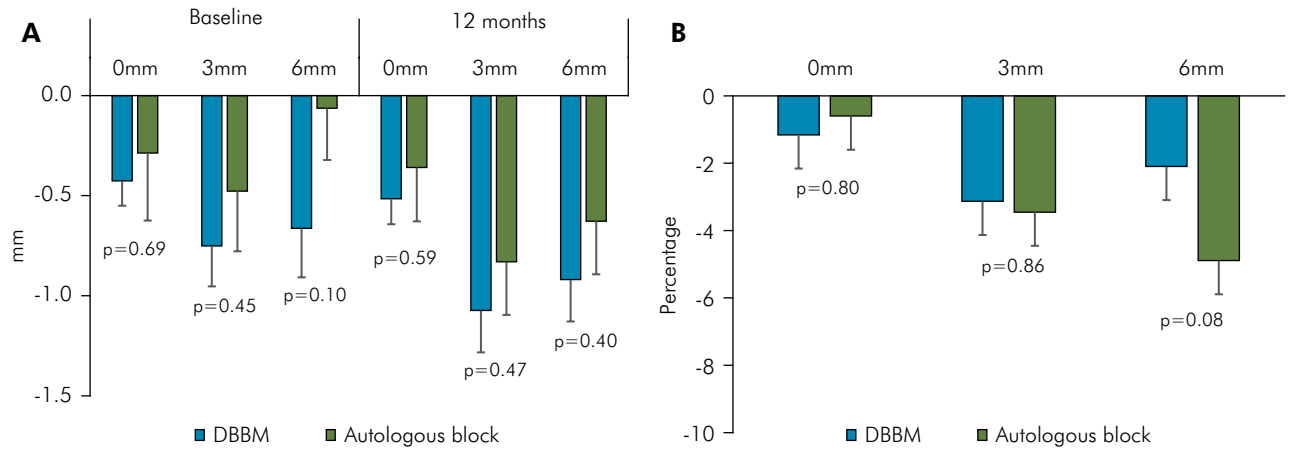

Figure 2. (A) Difference (mm) between the implant site and the contralateral tooth in facial-palatal ridge thickness at baseline and 12 months after crown installation at three different distances from the free gingival margin. (B) Percentage change in the facial-palatal ridge thickness (FPT) at implant site from baseline to 12 months.

in autologous block groups at the gingival margin after 12 months (p = 0.59). At 6mm from the gingival margin the difference was -0.7mm in DBBM and -0.1 mm autologous block groups at baseline (p = 0.10), and changed to -0.9mm and -0.6 mm after the 12 months (p = 0.40).

At all three measurements from the gingival margin, there was a negative change in FPT at the implant site (Figure 2B), indicating reduction in ridge thickness over time. This reduction averaged -1% in the DBBM group and -0.6% in autologous block group, at the gingival margin level (0 mm) (p = 0.80). At the 6mm height, the autologous block group lost approximately 5% compared to 2% in the DBBM group (p = 0.08).

The analysis adjusting for baseline differences in the size of the buccal defects is presented in Table 3.

Table 3. Simple and final multiple adjusted generalized estimating equations models for the comparison between DBBM and autologous graft in the difference of facial-palatal ridge thickness (mm) between the implant site and the contralateral tooth.

Variable	Simple models		Final multiple model	
	Beta±SE	p-value	Beta±SE	p-value
Group				
Bovine substitute	Reference		Reference	
Autologous bone	0.28 ± 0.20	0.21	0.49 ± 0.34	0.20
Distance from the gingival margin				
0 mm	Reference		Reference	
3 mm	-0.38 ± 0.10	< 0.001	-0.39 ± 0.09	< 0.001
6 mm	-0.17 ± 0.09	0.07	-0.17 ± 0.09	0.06
Time-point				
Baseline	Reference		Reference	
12 months	-0.27 ± 0.08	0.001	-0.27 ± 0.08	< 0.001
Apical size of buccal defect (mm)	-0.06 ± 0.05	0.38	-0.12 ± 0.08	0.10
Diameter of buccal defect (mm)	0.18 ± 0.16	0.26	0.10 ± 0.17	0.54

The unadjusted difference in FPT between groups equaled 0.28 mm (p = 0.21). When the model was adjusted for the size of the defect, the loss in ridge thickness was 0.49 mm higher in the autologous group, remaining without statistically significant difference (p = 0.20). Interestingly, the apical size of the defect did not influence FPT (coefficient = -0.12, p = 0.10).

All teeth in both groups were classified as having a thick gingival phenotype and were extracted due to root fracture. None of the implants were lost over the follow-up period resulting in 100% success rate in both groups.

All patients reported to use one single dose of ibuprofen immediately after surgery. There were no significant differences between groups in pain scores 24 and 48 hours after implant installation and grafting (Figure 3). The percentage of patients reporting no pain (VAS = 0) was 75% and 73% in the DBBM and autologous block groups, respectively (p > 0.05).

All patients in each group reported VAS scores equal to 100 for esthetic and functional satisfaction. There were no significant differences (p = 0.14) between groups for baseline OHIP scores [median and interquartile values: 10 (4–18) and 16 (8–25) for DBBM and autologous block groups respectively]. There was a significant reduction in OHIP scores in both groups. Median values reduced to 0 (interquartile values 0–2) in both groups after the follow-up period, without significant difference between groups at the end of the study (p = 0.68).

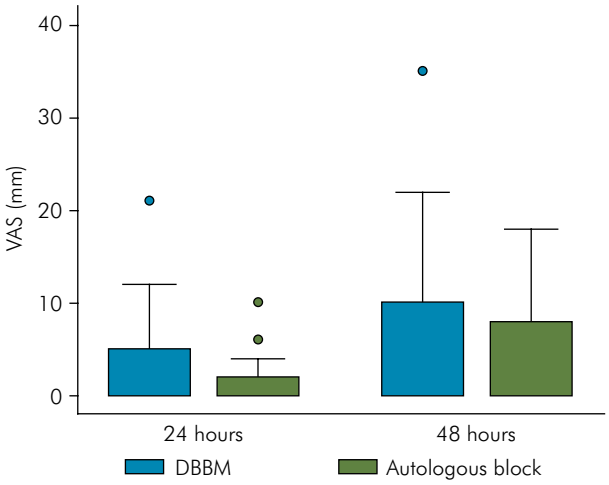

Figure 3. Boxplot of VAS scores for the two groups after 24 and 48 hours of the surgery.

The overall PES scores for DBBM and autologous block groups were 11.5 and 10.8 (p = 0.37), respectively (Table 4). There were no significant differences between groups regarding the overall PES score and for all 7 parameters evaluated. The differences

Table 4. Pink esthetic score (PES) for DBBM and autologous block groups.

Variable	% of highest score (PES = 2)			Mean values		
	DBBM	Autologous	p-value*	DBBM	Autologous	p-value**
Mesial papilla	78.6	76.9	0.99	1.7 ± 0.6	1.6 ± 0.6	0.93
Distal papilla	71.4	53.9	0.35	1.7 ± 0.5	1.5 ± 0.5	0.37
Soft-tissue level	64.3	76.9	0.47	1.6 ± 0.5	1.8 ± 0.4	0.49
Soft-tissue contour	92.9	76.9	0.24	1.9 ± 0.3	1.8 ± 0.4	0.26
Alveolar process	35.7	30.8	0.84	1.1 ± 0.8	1.1 ± 0.7	0.97
Soft-tissue color	57.1	53.9	0.99	1.5 ± 0.7	1.4 ± 0.6	0.88
Soft-tissue texture	78.6	53.9	0.31	1.8 ± 0.4	1.5 ± 0.7	0.13
Overall PES	-	-		11.5 ± 1.7	10.8 ± 1.9	0.37

*Chi-square test; **Independent samples t-test

Table 5. Peri-implant clinical parameters in the two groups at the end of the study.

Variable	DBBM (%)	Autologous (%)	p-value
Healthy implants	62.5	86.7	
Peri-implant mucositis	37.5	13.3	0.22*
Distribution of PPD			
2 mm	4.4	0	
3 mm	43.5	37.5	
4 mm	52.2	62.5	0.77*
Mean PPD (mm)	2.57 ± 0.53	2.87 ± 0.83	0.28**

PPD: peri-implant pocket depth; *Chi-square test; **Independent samples t-test

in the distribution of highest PES scores were also non-significant between groups.

The percentage of healthy implants was 62.5% in DBBM and 86.7% in autologous group (Table 5). The remaining implants presented peri-implant mucositis, and no peri-implantitis was detected after the follow-up period. There was no significant difference between groups in terms of PPD. Mean PPD equaled 2.57 ± 0.53 mm in the DBBM group and 2.87 ± 0.83mm in autologous group.

Discussion

The present RCT comparing two approaches for reconstruction of the buccal bone in conjunction with immediate implants in the presence of buccal defects demonstrated that: a) the two grafts resulted in stable ridge thickness over 1 year with overall reductions bellow half millimeter; b) compared to a contralateral tooth, ridge thickness was lower at the implant site after 1 year not overcoming 1mm and without significant differences between grafting groups; c) there was a reduction in the alveolar ridge at the implant site over 1 year, which was greater at the 6 mm distance from the gingival margin and was lower than 5%; d) esthetic outcomes in the clinical and patient perspectives were acceptable and did not differ between the two grafts.

This study showed that the dimensional reductions after 12 months of function were less than 0.5mm at the gingival margin for both DBBM and autologous block groups. Noteworthy, these results are comparable with those from the literature for immediate implants in intact sockets.[28-32] These findings suggest that immediate implants inserted in fresh sockets with buccal bone defects may lead to short-term findings similar to those expected in intact sockets in regards to ridge thickness. Importantly, in this study, sockets were in overall good conditions besides the buccal defect, respecting important factors related to the success of immediate implants such as intact bone at palatal and apical aspects, the presence of interproximal bone and possibility to predict the presence of papillae after crown installation, absence of gingival recession at the buccal site and periodontal disease.

The reduction in ridge thickness in both groups were very similar at the 0 mm and 3 mm height. Interestingly, at the 6mm height, there was a trend (p = 0.08) of a statistically higher loss of the ridge in the autologous group than DBBM (Figure 2A). However, the clinical relevance of the observed difference (5% compared to

2%) is very low, if not inexistent. There seem to be no reasons for the existence of a difference between the two grafts only at more apical areas of the ridge; therefore, we believe this finding was observed only by chance.

Another aspect that should be taken into consideration when interpreting the findings of this study is the increased risk of immediate implants compared to delayed implants that has been suggested in the literature.[9,33,34] In this regard, many studies about immediate implants highlight the importance of operator's skills and experience to achieve success with this approach.[8,29,35] The techniques applied in this study also require properly trained professionals, as well as all techniques of bone regeneration in the esthetic area. Therefore, the findings of the present study should be put into the context of very well-trained professionals; otherwise the success may not be achieved.

It has been demonstrated that bone from tuberosity has different cell differentiation patterns and turnover behavior compared to other intra-oral donor sites such as the mandible,[17] which would result in slow resorption rate over time. Other aspect favoring the autologous technique tested in this study was that a block of bone was used, which may also provide a different rate of resorption. In this regard, it has been demonstrated that bone chips from mandible do not provide good results due to rapid resorption,[36] but little is known about the comparison of bone block and chips in immediate implants. However, it became clear that these characteristics of the autologous grafting technique tested in this study (IDR) were unable to provide better outcomes than a bovine substitute, suggesting that the resorption rate was similar for both bone grafts in a short-term period. This finding corroborates those from a case series study,[15] but no other studies with better methodologies are available for comparisons. Noteworthy, to the best of the authors' knowledge, this is the first randomized controlled trial to assess dimensional changes that occur with the use of a block from the tuberosity compared to DBBM. Thus, further clinical and biological investigations are still needed.

The primary outcome of this study was the ridge thickness measured on casts, as it was defined during planning of the study and it was published in the registration of the trial (NCT03202030). Noteworthy, this is the first of a series of publications with the same sample, which will be followed for longer time periods and assessed for other secondary outcomes. In this regard, CBCTs are planned for a period of 2 years of follow-up, which will also allow a better evaluation of the stability of the grafts in a longer term rather than one year. At this moment, it is not possible to discriminate if changes in the alveolar ridge at the implant site are related to mucosa or to bone. This will be possible to discuss in the future with the analysis of CBCT images. Noteworthy, all cases included in this study had thick gingival phenotype before tooth extraction providing a better comparison of the two techniques tested in terms of soft tissue changes. Independently of that, the present findings indicate that the ability to maintain ridge thickness was not different between bovine and autologous grafts using an outcome that considers soft and bone tissues, as well as facial and palatal bone together.

There were no significant differences between groups regarding peri-implant health, (pocket depth, BOP) and clinical parameters of esthetics. It has been argued that one limitation of immediate implants is deep pocket depths. However, this is largely dependent on the tridimensional position of the implant, which was an important aspect controlled in this study. Mean PES scores were above 10, indicating good to high overall levels of esthetics.[27] Similar high PES scores were found in previous studies,[13,37,38] whereas others observed PES scores lower than those found in this study.[39]

The presence of a buccal defect was the major clinical feature of all cases included in this study. Defects were primarily identified in CBCT images and confirmed immediately after tooth extraction. This confirmation was done due to a limitation of CBCT to identify buccal bone when thickness is reduced and the high occurrence of bone wall thinner than 1 mm.[40] This is the reason the defects were confirmed after extraction, and randomization took place only after the confirmation of the presence of a defect. The size of the defect was measured clinically to provide the scenario in which the grafts were inserted. In this regard, it is important to acknowledge that the precise measurements of the buccal defect dimensions are limited during a flapless approach as used in this study. However, the large

size of most of the defects, as indicated by an average apical dimension of approximately 9 mm, allowed a clear determination of the presence of defect for all cases included in the study.

Both techniques tested in this study were not able to completely prevent tissue remodeling, as demonstrated by the comparisons between the implant site with the contralateral tooth. In a clinical perspective, this was also observed in the PES scores for the alveolar process convexity parameter, for which only approximately one third of the cases ended with an excellent condition (PES = 2) in the two groups. Despite this, both techniques managed to reduce tissue remodeling to esthetically acceptable levels in the patients' perspective, indicating that these ridge changes were not tangible for the patient.

In this study, there were no significant differences between DBBM and autologous groups in terms of pain, analgesic intake and patient satisfaction. Noteworthy, higher morbidity was expected in the autologous group due to the existence of a donor site. However, previous case reports also demonstrated very low morbidity after the same technique when very well trained and skilled professionals perform it. These patient-reported outcomes added to the overall findings of this study indicate that the two grafts can be chosen for reconstruction of the buccal defect in immediate implants in the patients' opinion. For the clinicians, the choice between the two grafting approaches seems to rely on costs and previous literature. The biomaterial tested in this study (Bio-Oss Collagen) has been largely used in guided bone regeneration procedures for decades with predictable outcomes, but requires investment by the patient that may be considered high in some socioeconomic scenarios. On the other hand, a block of bone from tuberosity has limited evidence, but may be harvested without relevant costs for patients.

The findings of this study should be interpreted considering some possible limitations of the study. The follow-up period of 1 year is still short for long-term bone and soft tissue stability. The accuracy of the models could also be questioned due to the possible compression of the soft tissues when taking the impressions with silicone; although all patients were subjected to the same compression not favoring one group or another. Moreover, there was a significant difference between groups in the size of the defects at baseline, but differences were in a small clinical magnitude and, after adjustment for this difference in multiple analytical models, the results remained the same indicating no impact on the comparisons between groups.

Conclusions

It can be concluded that DBBM with collagen membrane and a block of bone from the tuberosity did not differ in terms of alveolar ridge alterations, peri-implant clinical parameters and patients' satisfaction. Functional and esthetic results over a short-term period may be achieved after a single surgical act, with high acceptance by the patients and low morbidity.

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